

REMARKS

Claims 1 to 23 are pending.

I. Rejection under 35 U.S.C. § 103(a) as Unpatentable over Oishi *et al.*, Japanese Patent Application H5-194225 (“JP ‘225”)

Claims 1-23 are rejected under 35 U.S.C. § 103(a) as unpatentable over H5-194225 (“JP ‘225”) (“Oishi *et al.*”). Applicants respectfully traverse this rejection.

Applicants respectfully disagree with the Examiner’s characterization of Applicants’ remarks regarding Oishi et al. filed with the PTO on May 20, 2003. Indeed, Applicants were quoting from Oishi et al. In the Office Action, the Examiner commented that the Applicants alleged that Oishi et al. taught that amino acids alone do not stabilize benzimidazoles. Applicants respectfully direct the Examiner to page 11, paragraph (0016) where Oishi et al. state “[t]he use of buffering agent alone or the use of amino acid, amino acid salt or amino acid alkali salt alone provides absolutely no stabilization effect when the substance is blended with the benzimidazole compounds.” Applicants respectfully submit that Oishi et al. teach that an amino acid, such as glycine, when used alone does not provide any stabilization effect for a benzimidazole compound.

Nonetheless, claims 1-20 have been amended to recite limitations that are not disclosed by Oishi et al. and therefore claims 1-20 are not obviousness in view of Oishi et al.

Applicants respectfully request that the Examiner reconsider the rejection and withdraw it.

II. Rejection under 35 U.S.C. § 103(a) as Unpatentable over U.S. 5,536,735

Claims 1-23 are rejected under 35 U.S.C. § 103(a) as unpatentable over U.S. 5,536,735 (“‘735” patent) (“Takechi *et al.*”). Applicants respectfully traverse this rejection.

Applicants respectfully disagree with the Examiner’s characterization of Applicants’ remarks regarding Takechi et al. filed with the PTO on May 20, 2003. The Examiner states

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“applicants argue that Takechi et al. only teach of using amides to stabilize benzimidazoles rather than the instantly claimed amino acid glycine. In addition, applicants allege that sugars are the preferred form regulators.” (Office Action dated January 28, 2004).

Firstly, Takechi *et al.* state in the ‘735 patent that, “the benzimidazole compound having antiulcer activity is highly soluble in an aqueous solution of an amide, such as nicotinamide or benzamide, and remains quite stable in such solution and that a composition obtainable by dissolving the compound in such an aqueous amide solution and lyophilizing or spray-drying the solution shows no coloration with time and offers a long shelf-life as well as good water-reconstitutability” (column 1, lines 52-59). This statement demonstrates that Takechi characterizes his invention as the stabilization of benzimidazoles using nicotiamides. Takechi goes on to state at column 1, lines 64-67, “[a]ccording to this invention, there is provided: 1) [a] pharmaceutical composition which comprises a benzimidazole compound having antiulcer activity and a water-soluble carboxylic acid amide...” No mention is made of the use of glycine until col. 8, line 17, and then it is mentioned as a buffering agent for use in strongly basic solutions, NOT as a deterrent to discoloration. While the the words “benzimidazole” and “glycine” appear in Takechi, it is not teaching, much less suggesting, the stabilization of benzimidazoles using glycine.

Secondly, the Examiner states “applicants next allege that sugars are the preferred form regulators of Takechi et al.” The Examiner next states: “Takechi may list preferred regulators as sugars.” Applicants disagree with the Examiner’s characterization of Applicants’ remarks filed May 20, 2003. Quoting Takechi: “[p]referred among these form regulators, are sugars.” (Col. 8, lines 47-48.) Thus, Takechi clearly states that sugars are the preferred form regulators.

Lastly, applicants respectfully disagree with the Examiner’s statement that “Takechi et al. clearly teach of a composition and methods of stabilized compositions that are comprised of benzimidazole and glycine.” (Office Action dated January 28, 2004, page 4, line 1.) In contradistinction, Takechi clearly teach that his invention in its broadest form is a pharmaceutical composition comprising benzimidazoles and water soluble carboxylic acid amides, with the water soluble carboxylic acid amides imparting the discoloration prevention. (Takechi et al.,

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Claim 1, col. 12, line 65-67). Applicants respectfully submit that it is overreaching to state that “Takechi et al. clearly teach of a composition and methods of stabilized compositions that are comprised of benzimidazole and glycine.” Instead, Takechi et al. clearly teaches a pharmaceutical composition comprised of benzimidazole and water soluble carboxylic acid amides.

Nonetheless, claims 1-20 have been amended to recite limitations that are not disclosed by Takechi *et al.* and therefore claims 1-20 are not obviousness in view of Takechi *et al.*

Applicants respectfully request that the Examiner reconsider the rejection and withdraw it.

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CONCLUSION

Applicants respectfully submit that all the bases for rejection of the pending claims are now moot. The Examiner is requested to reconsider the rejections and to withdraw them and to pass this case to issuance.

Respectfully submitted,

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Hollie L. Baker
Hollie L. Baker
Registration No. 31,321

Wilmer Cutler Pickering Hale and Dorr LLP
60 State Street
Boston, MA 02109
617 526-6110 (Telephone)
617 526-5000 (Fax)